REMARKS

Status of the claims

Claims 28-43 are pending in the application. Claims 33-37 have been withdrawn. By this amendment, Claims 30 and 41 have been cancelled without prejudice or disclaimer of any previously claimed subject matter. Claims 28 and 38 have been amended by incorporating limitations of claims 30 and 41 into claims 28 and 38, respectively. Upon entry of this amendment, claims 28-29, 31-40, 42-43 are pending in the application. Claims 28, 29, 31, 32, 38, 39, 40, 42, and 43 are under consideration.

Applicants respectfully reiterate request for rejoinder of presently excluded method claims, to the extent that they incorporate all the limitations of the product claims. Applicants request that the Examiner reconsider this request in view of the newly amended claims.

With respect to all amendments and canceled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Objections on specification formalities

Applicants respectfully submit that the current status of application 08/118,053 has been updated.

With respect to the naming of the peptides on page 24, Applicants respectfully submit that peptide #1, which contains 8 residues, was referred to as a "7mer" because it contains 7 residues from the Melittin sequence. Similar nomenclatures were used for other peptides in listed on page 24 of the specification.

Accordingly, Applicants respectfully request that the objections be withdrawn.

Rejection under 35 U.S.C. §112, second paragraph

Claims 28-32 and 38-43 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner reasoned that, in claim 28, it was not clear whom or what an "individual" is. Similarly in claim 38, the Examiner stated that it was not clear what the source of the T cell is that would be used to measure the T cell stimulation index.

Applicants respectfully traverse and submit that the claims are clear. However, in the interest of expediting prosecution, Applicants have amended the claims as the Examiner suggested by inserting limitations of now cancelled claims 30 and 41 into claims 28 and 38, respectively. Accordingly, withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §112, first paragraph (written description)

Claims 31 and 42 are rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement.[1]

The Examiner stated that the term "buffer" in claims 31 and 42 was not adequately supported in the specification. Although the Examiner acknowledged that the specification teaches specific example of a buffer (see, e.g., page 13, lines 26-27, "each peptide (40 mg) was dissolved in 0.1 M sodium borate buffer, pH 9.0"), he asserted that there was no written description for a "generic" buffer. Applicants respectfully traverse this rejection.

Applicants respectfully note that "an applicant need not describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Moba v. Diamond Automation, Inc.*, 325 F.3d 1306 (Fed. Cir. 2003), quoting *Union Oil Co. of Cal. v. Atlantic Richfield*, 208 F.3d 989, 997 (Fed. Cir. 2000); *See also Lampi Corp. v. American Power Products ,Inc.*, 56 U.S.P.Q.2d

[1] The Office Action referred to as "Claims 31-32." See page 3 of the Office Action. Based on the rejection, however, Applicants assumed that the rejection did not apply to claim 32.

1445 (Fed. Cir. 2000)("The disclosure as originally filed need not provide in haec verba support for the claimed subject matter at issue."). An objective standard for determining compliance with the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. MPEP 2163.02.

At the time the present application was filed, buffers suitable for dissolving peptides were well known in the art. Given the teaching in the present application, one of ordinary skill in the art will readily recognize that the buffer used in the application is provided merely as an example, and that any other suitable buffer can be used to substitute the buffer taught therein. Accordingly, Applicants respectfully submit that the specification provides adequate support for "buffer." Accordingly, Applicants respectfully request withdrawal of the rejection.

Rejection under 35 U.S.C. § 101

Claims 32 and 43 are rejected under 35 U.S.C. § 101 for allegedly lacking substantial utility or a well-established utility. The Examiner stated that although Applicants have described complexes of the immunogen analogs and antibodies as being formed in immunoassays, they have not disclosed a use for the complex *per se*. Applicants respectfully traverse this rejection.

Applicants submit that the specification discloses a substantial utility for the claimed complex. For example, as the Examiner stated, the specification discloses immunological assays (i.e., formation and detection of immunogen analog-antibody complexes) for the purpose of screening specific immunogen analogs. The immunogen analog-antibody complex disclosed therein serves as an indicator for the ability of the immunogen analog to bind specifically to serum antibodies. Such utility is substantial because immunoassay defines a "real world" context of use in identifying useful immunogen analogs.

Additionally, the utility requirement is satisfied because there is a well-established utility for the claimed complex. *See* MPEP 2107.02.II.B ("An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful

based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial and credible.").

Applicants respectfully submit that a person of ordinary skill in the art would immediately appreciate that the immunogen analog-antibody complex disclosed in the specification serves as an indicator for the ability of the immunogen analog to bind specifically to serum antibodies during screening of useful immunogen analogs. Indeed, the Examiner himself states that the specification discloses immunological assay (i.e., formation and detection of immunogen analog-antibody complexes) "for the purpose of identifying useful immunogen analogs." See page 4, lines 3-4 of the Office Action.

Accordingly, Applicants respectfully submit that the complex claimed in claims 32 and 43 does have substantial and well-established utility, and respectfully request that the rejection be withdrawn.

Claims 32 and 43 are also rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to teach how to use the complexes. As discussed above, the specification teaches use of the immunogen analog-antibody complex, for example, in an immunoassay for screening useful immunogen analogs. Applicants therefore respectfully request withdrawal of the rejection.

Rejection under 35 U.S.C. §102

Tanihara et al.

Claims 28-29, 31-32, 38-40, and 42-43 are rejected under 35 U.S.C. §102(a) or §102(e) as allegedly being anticipated by Tanihara et al. (4,925,787). Tanihara et al. was cited as teaching an anti-idiotypic monoclonal antibody that binds to an autoantibody against the nicotinic acetylcholine receptor (AChR). The Examiner reasoned that the anti-idiotypic antibody lacks T cell epitopes capable of activating T-cells in an individual where the "individual" is the mouse used to produce the anti-idiotypic antibody. Claims 30 and 41 are not rejected because the Examiner stated that "the 'individual' recited in dependent claims 30 and 41 could not be this mouse."

Without acquiescing to the rejection, and in the interest of expediting prosecution, Applicants respectfully submit that the claims as amended recite "an individual having an antibody mediated pathology," a limitation that was previously recited in claims 30 and 41. Accordingly, Applicants respectfully request withdrawal of the rejection.

Milich et al.

Claims 28-29, 31-32, 38-40, and 42-43 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Milich et al (4,599,231). Milich et al. was cited as teaching polypeptides of Hepatitis B virus antigen (HBsAg) that comprise a B-cell determinant (epitope) but lack T cell epitope. The Examiner stated that such peptides could be considered as analogs of the immunogen HBsAg and thus fall within the scope of the present claims.

Without acquiescing to the rejection, and in the interest of expediting prosecution, Applicants respectfully submit that the claims have been amended by incorporating limitations of claims 30 and 41, two claims that were not rejected by the Examiner, into claims 28 and 38, respectively. Accordingly, Applicants respectfully request the rejection be withdrawn.

Good et al.

Claims 28-30, 31-32, 38-40, and 42-43 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Good et al. (4,886,782). Good et al. was cited as teaching that the (NANP)n polypeptide, which is a subsequence of the malaria circumsporozoite (CS) protein, elicits T-cell dependent immune response only in certain strains of mice. The Examiner thus concluded that the (NANP)n polypeptide can be considered as an analog of the immunogen CS protein and falls within the scope of the present claims.

Without acquiescing to the rejection, and in the interest of expediting prosecution, Applicants respectfully submit that the claims have been amended by incorporating limitations of claims 30 and 41, two claims that were not rejected by the Examiner, into claims 28 and 38, respectively. Accordingly, Applicants respectfully request the rejection be withdrawn.

Rejection under nonstatutory double patenting

Claim 28 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,060,056. Applicants will address this issue upon indication of otherwise allowable subject matter.

Final note on reference lined out by Examiner

Attached herewith are copies of three of the references lined-out by the Examiner (References 36, 54, and 86) along with a Form 1449. Reference 90 is a duplicate of Reference 108 and thus was not included. Applicants respectfully request that the Examiner consider these references and initial the Form 1449 accordingly.

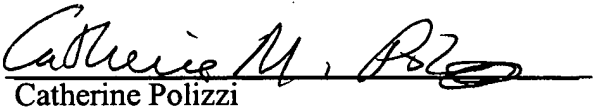
CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 252312006002.

Respectfully submitted,

Dated: March 21, 2005

By: 

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